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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,870	07/24/2006	Iris Bahir	1120-PCT-US	1448

Albert Wai-Kit Chan
Law Offices of Albert Wai-Kit Chan
World Plaza Suite 604
141-07 20th Avenue
Whitestone, NY 11357

EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,870	BAHIR ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) 26-29, 34-38 and 45-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 30-33 and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/8/2007; 4/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 25-48 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 25, 30-33 and 39-44 in the reply filed on 7/10/2007 is acknowledged.

Applicants contend that that claim 25 is drawn to a method of generating genetically diverse plants via the incorporation of exogenous microsatellite sequence into the plant genome; that microsatellite sequence is a well-known term in the art, and one of ordinary skill in the art would readily understand and recognize what is a microsatellite sequence; and that one of ordinary skill in the art would not define or accept cDNA with oligo dT as microsatellite sequence. LeClere et al. only teach cDNA library; LeClere et al. do not teach or suggest a method of using microsatellite sequence.

The Office contends that oligo(dT) meets the definition of MS-like DNA fragment by comprising a monotonous repeat of one to six nucleotides and being at least twelve nucleotides in length. Further, LeClere et al. teach all the steps of the instant methods. Therefore, LeClere et al. anticipate the method of claim 25.

Claims 26-29, 34-38 and 45-48 are withdrawn for being drawn to non-elected inventions.

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Claims 25, 30-33 and 39-44 are examined on the merits.

The requirement is deemed proper and is therefore made FINAL.

Claim Objections

3. Claim 25, line 9 is objected to for not reciting – and – after the recitation “fragments”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25, 30-33 and 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitations “the generation” in line 1 and “the incorporation” in line 2. There is insufficient antecedent basis for those limitations in the claim.

In claim 25, line 11, the recitation, “suitable conditions”, renders the claim indefinite. It is unclear what condition it refers to. The metes and bounds are not clear.

In claim 30, the recitation, “suitable vectors”, renders the claim indefinite. It is unclear what vectors it refers to. The metes and bounds are not clear.

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Regarding claims 31 and 33, the phrase "preferably" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 40 and 41 recite the limitation "said DNA fragment" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims. Claim 25 recites "MS-like DNA fragments".

Regarding claim 40, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 42 recites the limitation "said exogenous DNA" in line 2. There is insufficient antecedent basis for this limitation in the claims.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25, 30-33 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for the generation of genetically diverse plants via the incorporation of exogenous microsatellite (MS) sequence into the plant genome, wherein said plants are of the same species, and said method comprises the following steps: (a) obtaining MS-like DNA fragments; (b) introducing said DNA fragments into plant cells; (c) selecting the plant cells containing said DNA fragments; (d) cultivating the plants grown from the selected cells, under suitable conditions; and plants produced by said method.

The office interprets that the claims to encompass any MS sequence from any organism.

The specification teaches transforming MS-like DNA fragments of SEQ ID NO: 1-5 into tobacco cells using the particle bombardment method (page 17, last paragraph to page 19, last paragraph). Several other MS like DNA fragments are also disclosed in the specification (specification, page 1, 3rd paragraph; page 7, 3rd paragraph).

Applicants do not describe any other MS like DNA fragments except for the ones discussed above. Applicants also do not correlate the conserved structures of MS like DNA fragments with the function thereof.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise

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definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of MS DNA fragments falling into the claimed genus encompassing all the MS DNA fragments in plant. Applicants only disclose the species as discussed above. Applicants also do not disclose structural features common to members of the claimed genus. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Scope of Enablement

6. Claims 25, 30-33 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the generation of genetically diverse plants via the incorporation of one of the exogenous

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microsatellite(MS) sequences of SEQ ID NO: 1-5, does not reasonably provide enablement for a method for the generation of genetically diverse plants via the incorporation of any exogenous microsatellite(MS) sequence into the plant genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for generating genetically diverse plants via the incorporation of exogenous microsatellite (MS) sequence into the plant genome, wherein said plants are of the same species, and said method comprises the following steps: (a) obtaining MS-like DNA fragments; (b) introducing said DNA fragments into plant cells; (c) selecting the plant cells containing said DNA fragments; (d) cultivating the plants grown from the selected cells, under suitable conditions.

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The office interprets that the claims encompass any MS sequence from any organism or even a poly A as defined by Applicants (specification, page 1, 3rd paragraph).

The specification teaches transforming MS-like DNA fragments of SEQ ID NO: 1-5 into tobacco cells using the particle bombardment method (page 17, last paragraph to page 19, last paragraph). Several other MS like DNA fragments are also disclosed in the specification (specification, page 1, 3rd paragraph; page 7, 3rd paragraph).

The specification fails to provide guidance on how to obtain MS-like DNA fragments from all the plants. The only MS-like DNA fragments disclosed in the specification are SEQ ID NO: 1.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of homologous genes as probes or by designing primers to undisclosed regions of homologous genes and isolating or amplifying fragments, subcloning the fragments, producing transformation vectors and transforming plants therewith, in order to identify those, if any, that when inserted have desirable phenotypes.

Therefore, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 25, 30-33 and 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by LeClere et al (2001 Plant Molecular Biology 46:695-703).

The claims are drawn to a method for the genetically diverse plants via the incorporation of exogenous microsatellite (MS) sequence into the plant genome comprising introducing MS-like DNA fragments into plant cells and selecting and cultivating plants comprising said DNA fragments; or wherein optionally the MS-like DNA fragments obtained in step (a) are ligated into suitable vectors and then proceed to step (b); or wherein the exogenous MS is preferably introduced concomitantly with a selective marker of a kanamycin resistant gene; or wherein said DNA fragment is introduced via any one of electroporation, chemical, mechanical means or liposomes; wherein said DNA fragment is introduced by a genetic vehicle such as a plasmid or a viral vector; or wherein said DNA fragment is obtained via synthesis or cloning; wherein said exogenous DNA is produced by the ligation of several DNA pieces; or wherein the generation of genetically diverse plants further includes the generation of one of cells,

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seeds or progeny of said plants; or a plant variety produced by the method of claim 25, and cells, seeds and progeny thereof.

The Office interprets that "mechanical means" of transformation encompasses any transformation methods.

LeClere et al. teach that cDNAs of Arabidopsis with oligo (dT) were generated and the binary vectors containing the cDNA library were transformed into Arabidopsis (abstract; Figure 1; also the paragraph bridging pages 697-698). Transgenic lines were selected and the transgenic plants were further screened for morphological and pigmentation alteration (page 699, 2nd paragraph of the right column). LeClere et al. also teach that a kanamycin resistant gene is used as selection marker (page 697, Figure 1). LeClere et al. also teach that the cDNA inserts are ligated into the 35S BARB vector and that the vector is introduced by Agrobacterium mediated transformation. (paragraph bridging pages 697-698).

Given that the cDNA with oligo dT meets the definition of MS-like DNA fragment by comprising a monotonous repeat of one to six nucleotides and being at least twelve nucleotides in length, the reference anticipates the method.

Conclusion

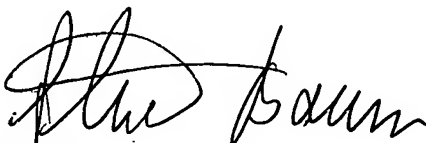
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


STUART F. BAUM, PH.D.
PRIMARY EXAMINER

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